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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/893,759	07/11/1997	KAZUNORI SAITOH	1587-0024-0	8270

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/16/2002

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/893,759

Applicant(s)
Saitoh et al

Examiner
Chris Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 26, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-42 is/are pending in the application.
- 4a) Of the above, claim(s) 17, 31, 36-38, and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-16, 18-30, 32-35, and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 7-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of apoprotein B in Paper No. 32 is acknowledged. The traversal is on the ground(s) that the a serious burden has not been established in searching all of the species. This is not found persuasive because a search for each of the species would require a different search strategy and different search terms to search each and all of the species. Such a search would constitute a serious burden on the Examiner.

Claims 7-16, 18-30, 32-35, and 39 will be examined in accordance with Applicant's election of apoprotein B.

Claims 17, 31, 36, 37, 38, 40, 41, and 42 are non-elected claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 U.S.C. § 112

2. Claims 7-16, 18-30, 32-35, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 21 are vague because they fail to recite a correlation step that relates the detected agglutinates to the presence of the antigen as required in the preambles of the claims.

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Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7, 10-13, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strahilevitz in view of Schmidtberger or Young et al.

Strahilevitz (U.S. Patent 4,375,414) discloses an agglutination immunoassay for determining a hapten, such as drug or steroid, in a sample wherein a sample is mixed with an agglutinable carrier-bound anti-hapten antibody in suspension and then mixed with a free anti-hapten antibody. If sample contains above a minimal amount of the free hapten, agglutination results. Although erythrocytes are the preferred carrier, other materials, such as latex or other particles, are also useful (col. 3, lines 15-37). This method has the advantage of indicating the presence of hapten by hemagglutination rather than by hemagglutination inhibition (col. 7, example 5).

Stahilevitz differs from the instant invention in failing to teach the use of antibodies specific for apoprotein B.

Schmidtberger (U.S. Patent 5,180,679) discloses an agglutination assay using particles with antibodies specific for Apo B (i.e. apoprotein B) (cols. 1-2).

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Young et al (U.S. Patent 5,460,947) discloses 2 monoclonal antibodies that are specific for apolipoprotein B-100 (i.e. apoprotein B) (cols. 3-5). The disclosed antibodies can be immobilized onto various types of particles (cols. 25-26).

It would have been obvious to one of ordinary skill in the art to use antibodies specific for apoprotein B, as taught by Schmidtberger or Young et al, in the agglutination assay of Strahilevitz because the analyte, in this case apoprotein B, that is to be detected dictates the reagents (i.e. the antibodies of Schmidtberger or Young et al) that would be used in the agglutination assay of Strahilevitz.

5. Claims 21-27, 29, 30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer Mannheim GMBH in view of Schmidtberger or Young et al.

Boehringer Mannheim GMBH (EP 617 285 A2), hereinafter EP '285 A2, discloses an agglutination immunoassay for determining analyte by binding analyte to a receptor R1 which is immobilized on a particulate carrier and a soluble receptor R2 (i.e. free antibody) which is specific for an analyte and has at least two binding sites for the analyte (page 3, paragraph 3). R1 and R2 may independently be monoclonal antibodies,, polyclonal antibodies, or antibody fragments (page 3, paragraph 5 and 7). Preferably, the reaction mixture also contains an accelerator, such as 6 kd polyethylene glycol (page 5, paragraph 2). The particulate carrier is any desired particulate carrier that is known in the state of the art for performing agglutination tests, preferably latex particles, metal sols and liposomes, with sizes ranging from 10 to 500 nm (page

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5, paragraph 3). The analyte is any substance that has at least two epitopes, preferably proteins or human chorionic gonadotropin (page 5, paragraph 5). Analyte concentration can be determined with suitable equipment either by nephelometry or by turbidimetry by comparison to a standard curve of known analyte concentration (page 5, paragraph 6).

Boehringer Mannheim GMBH differs from the instant invention in failing to teach the use of antibodies specific for apoprotein B.

See above for the teachings of Schmidtberger and Young et al.

It would have been obvious to one of ordinary skill in the art to use antibodies specific for apoprotein B, as taught by Schmidtberger or Young et al, in the agglutination assay of Boehringer Mannheim GMBH because the analyte, in this case apoprotein B, that is to be detected dictates the reagents (i.e. the antibodies of Schmidtberger or Young et al) that would be used in the agglutination assay of Boehringer Mannheim GMBH.

6. Claims 7-16, 18-30, 32-35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragle et al in view of Strahilevitz, Boehringer Mannheim GMBH, Schmidtberger, and Young et al.

Cragle et al (WO 85/02258) discloses an improved nephelometric immunoassay for an antigen in a fluid sample comprising contacting the sample with both a solid phase antibody and liquid phase antibody and measuring the amount of formed complexes, i.e. agglutinates, wherein

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the Hook effect is avoided (page 7, paragraph 2). The antibodies are independently monoclonal or polyclonal (page 9, paragraph 6).

Cragle et al differs from the instant invention in failing to teach sequential contact of two antibodies; use of a calibration curve; all of the specifically claimed carrier types; use of an immune-reaction accelerating compound, such as 6 kd polyethylene glycol; and use of antibodies specific for apoprotein B.

See above for the teachings of Strahilevitz, Boehringer Mannheim GMBH, Schmidtberger, and Young et al.

It would have been obvious to one of ordinary skill in the art to modify the method and reagents of Cragle et al by contacting sample with the solid phase and liquid phase antibodies sequentially as suggested by Strahilevitz (solid phase antibody first followed by liquid phase antibody) or EP '285 A2 (liquid phase antibody first followed by solid phase antibody) to directly indicate analyte (Strahilevitz) or optimize sensitivity and range (EP '285 A2); use a calibration curve as suggested by EP '285 A2 to obtain quantitative results; to use any solid phase carrier typically used in agglutination assays, as suggested by EP '285 A2 for the same intended purpose; and to use a known immune-reaction accelerating compound, such as 6 kd polyethylene glycol, as suggested by EP '285 A2 to save time.

It also would have been obvious to one of ordinary skill in the art to use antibodies specific for apoprotein B, as taught by Schmidtberger or Young et al, in the agglutination assay of Cragle et al because the analyte, in this case apoprotein B, that is to be detected dictates the

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reagents (i.e. the antibodies of Schmidtberger or Young et al) that would be used in the agglutination assay of Cragle et al.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
July 14, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641